Effect of Low FODMAP Diet on Irritable Bowel Syndrome and Functional Dyspepsia Overlap.

SHORT SYNOPSIS

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by

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Certificate

I hereby declare that the short synopsis titled "Effect of Low FODMAP Diet on Irritable Bowel Syndrome and functional dyspepsia overlap." being submitted in partial fulfilment of the requirement for the degree of Doctor of Philosophy in the Department of Nutrition and Dietetics under School of Allied Health Sciences of Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2024. It is a bonafide record of original work carried out under the supervision of Dr. Gurseen Rakhra and has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

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ABSTRACT

Evidence from various researches have suggested the association between the consumption of food rich in fermentable oligosaccharide, disaccharide, monosaccharide and polyols with symptoms arising from irritable bowel syndrome (IBS) as well as functional dyspepsia (FD). Although, the pathophysiology of IBS as well as FD is limited to none, current knowledge associates it with altered function of the gut barrier, impaired intestinal and gastroduodenal sensitivity, intestinal and gastroduodenal inflammation and dysbiosis of the gut microbiota. Clinically, there is an increased probability of IBS-FD overlap in case of severe gastrointestinal symptoms like pain in the abdomen and/or disordered bowel habit with treatments that are aimed to reduce these symptoms. Certain dietary components are thought to exacerbate their symptoms. Therefore, there has been an emphasis on dietary management of the condition. There has been a paradigmatic shift in the treatment of IBS and FD with the introduction of diet low in fermentable oligosaccharide, disaccharide, monosaccharide and polyols- low FODMAP diet. Various experimental studies have used low FODMAP diet as an intervention to treat IBS or FD. However, there is a critical need for a study to substantiate if low FODMAP diet is beneficial for treating IBS-FD overlap. There is no trial as per our search to evaluate the impact of low FODMAP diet on the overlap of IBS and FD. Apart from this, there is no data that evaluates the reintroduction phase of the low FODMAP intervention in IBS-FD overlap. Therefore, through this research we would like to build an association between reduced symptoms of IBS-FD overlap with a low FODMAP diet in comparison to traditional dietary advice.

Keywords: IBS, dyspepsia, low FODMAP, gut dysbiosis, IBS-FD overlap

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Description of Broad Area

Gastrointestinal (GI) disorders are coming out to be relatively common in clinical settings. They can be identified as disorders with their pathophysiological mechanism involving- alteration in motility of the gut, dysregulation of the intestinal barrier, the gut immune system dysfunction, malabsorption of the bile acid, alteration in Gastrointestinal secretion, gut microbiome dysbiosis and changes occurring in gut-brain axis. Irritable bowel syndrome and functional dysbiosis are the most common GI disorders with a substantial overlap (Singh et al., 2022). Irritable bowel syndrome (IBS) is known as a functional disorder of the gastrointestinal system wherein patients suffering from the disorder experience altered bowel habits, abdominal pain, either of the following IBS subtype- constipation (IBS-C), diarrhea (IBS-D), both (IBS-M) or un-subtyped (IBS-U) (Canavan et al., 2014) (Yao et al., 2012). Due to no definitive biomarker, diagnosis of IBS takes place clinically (Chaudhary & truelove, 1962). Standardized diagnostic criteria like Manning, Kruis and most recent Rome criteria were developed (Khan & Chang, 2010). According to multiple studies, the prevalence of IBS in India ranges from 4.2%-7.5% (Rahman et al., 2017). A number of treatment options for IBS are currently available like diet, antispasmodics in some cases, psychological and behavioral therapy, probiotics, acupuncture, herbal therapy etc. which are individualized as per the patient and practitioner preference (Khan & Chang, 2010). Functional dyspepsia (FD) is a combination of various symptoms occurring in the gastro-duodenal region of the gastrointestinal (GI) tract. The symptoms of which involve epigastric pain or burning, early satiety or feeling of fullness after having a meal. From the limited data available, it was concluded that the prevalence of FD in India is reported in a wide range of 7.6% to 49% (Ghoshal & singh, 2012). FD has been divided into two subgroups namely- Epigastric pain syndrome (EPS) and Post-Prandial Distress Syndrome (PDS). PDS is characterised by epigastric pain, early satiation, post prandial fullness followed by meal whereas EPS has no association with timing of a meal (Singh et al., 2022). Risk factors of FD include acute gastroenteritis, frequent smoking, use of NSAIDs (non-steroidal anti-inflammatory drugs), psychological co-morbidity, female gender and *H. Pylori* infection (Ford et al., 2015).

It is important to note that FD co-exists with number of other conditions like IBS, gastro-oesophageal Reflux Disorder, migraine, overactive bladder, chronic fatigue etc. (Ford et al., 2020). It is said that an individual may possess any one of the IBS

diagnosis- constipation, diarrhoea, bloating or distention. However, one of these bowel disorder can be accompanied by other disorder of any part of GI tract, the condition we refer to as an overlap (Sperber et al., 2022). According to a study there is an eight fold higher chances of IBS occurring in patients with FD (Ford et al., 2010). The global risk factors that are attributed to trigger these Functional gastrointestinal Disorders (FGIDs) now termed as Disorders of Gut-Brain Interaction (DGBI) include lower family income, low education status, tobacco, consumption of aerated drinks, frequent consumption of tea/coffee, diet, disturbed sleep. There is a researched difference in IBS-FD risk factors between India and western countries when we consider dietary and social pattern. The influencing factors being vegetarianism, increased use of chili/spices and milk/dairy products, tobacco, alcohol consumption, employment status etc (Ghoshal & Singh, 2017). The literature has well defined the role of food in exacerbating the gastrointestinal disease symptom (Cancarevic et al., 2020) Therefore, apart from pharmacological interventions, some of the non-pharmacological interventions such as diet modification has gained importance in recent times (Goyal et al., 2020). Diet is known to have an indirect impact on health which can be mediated by the gut microbiome. The growing body of research on diet and microbiome suggests that the impact of diet is largely personalised depending on host genetics, anthropometrics, gut microbiome diversity etc. (Perler et al., 2023). Current dietary modifications for IBS include 1. Traditional dietary advices 2. Low FODMAP 3. Gluten free diets (Goyal et al., 2020). A low FODMAP diet is a relatively novel approach especially in India for treatment of FGIDs. Asian diet being different from western diet is high in foods with FODMAP content which includes onion, garlic, pulses, wheat and wheat based products. (Ghoshal & Singh, 2017). As recognised by number of studies, a diet having high FODMAP content can result in symptoms associated with IBS and FD in context to gastroduodenal sensitivity. Therefore, diet low in FODMAP resulted to be beneficial in lowering the symptoms of gastrointestinal disorders by 30% (Staudacher et al., 2021). Reduction in FODMAP availability during a Low FODMAP diet regime limits small intestinal water, reduction in mechanoreceptors stimulation leading to reduction in symptoms like epigastric pain, postprandial fullness, and bloating. IBS-FD, though not the contributors to mortality, can lead to a significant decline in an individual's quality of life. Carbohydrates are responsible for the production of colonic gas which can have an impact on functions of the upper

gastrointestinal part leading to symptoms in upper gastrointestinal tract. Low FODMAP diet can also increase integrity of the gastrointestinal epithelium and reduction in immune activation (Major et al., 2017) (Swanson et al., 2020). Also, the low FODMAP is likely to work by reducing the intestinal lumen's concentration of unabsorbed, osmotically active short chain carbohydrates, which causes the small intestinal water content to drop which probably has a positive impact on gastrointestinal signs and symptoms. Additionally, because fewer of these carbs enter the colon, the microbiota's fermentation activity is diminished, which lowers the formation of colonic gas (Nistal et al., 2012). As far as Indian population is concerned, the statement 23 of The Indian Consensus Statements on Irritable Bowel Syndrome in Adults that Dietary FODMAP restriction is useful in a proportion of IBS patients was accepted completely by the members of the committee comprising of Indian Neuro-gastroenterologists (Ghoshal et al., 2023). India, especially is a country with regional differences in dietary composition. A study by Mustafa & Ghoshal, 2022 found that in southern and eastern India, implementing a low-FODMAP diet may be relatively easy in western India, and difficult in central and northern India. Numerous studies have used low FODMAP approach in order to treat IBS and FD separately (Goyal et al., 2021) (Goyal et al., 2022). Although beneficial, low FODMAP diet was found to decrease the overall abundance of the microbial diversity with a higher faecal pH in a study done by Halmos et al., in 2015. Furthermore, no study has utilised the low FODMAP diet in IBS-FD overlap when compared to traditional dietary advice. This multicentric study aims to assess the effect of low FODMAP diet on IBS-FD overlap patients of a gastroenterology outpatient department of hospitals.

Literature Review

In a study by Ghoshal & Singh, 2017, 4.1% out of the total study population of 2774 had dyspepsia-IBS overlap. Their study also stated that 21.7% patients suffering from functional dyspepsia had IBS co-existing with it and 60.5% patients suffering from IBS had co-existing dyspepsia. Wulffen et al., 2019 established in their study of 120 patients that the FD-IBS overlap is more common (63%) than unusual in the clinical context. FD-IBS overlap is linked to a more serious FGID presentation. Over previous years, IBS-FD overlap has been identified by numerous studies using various criteria such as Manning, Rome I, II and III. In an India study, it was discovered that 14.2% out of the 2,549 participants had both dyspepsia and IBS. In this study, dyspepsia was defined as pain and discomfort occurring in the upper abdominal region that persisted for a period of minimum one month, and IBS was identified using Manning's criteria (Mahadeva & Goh, 2006). In a study carried out in Hong Kong, by using Rome I criteria, 14% out of the 1649 subjects had IBS-FD overlap (Hu et al., 2002). Using the Rome II criteria, 4.4% of 181 medical students in a Japanese study exhibited dyspepsia and IBS overlap and 11% of the 476 individuals in a Korean study showed dyspepsia and IBS overlap (Hori et al., 2009) (Kim et al., 2004). Following the Rome III criteria, 5% of the 3,014 participants in a Chinese study had dyspepsia and IBS together (Wang et al., 2008).

Tan et al., 2017 states that FODMAPs are a group of fermentable short-chain carbohydrates that are present in a variety of meals. All subjects experience inadequate absorption of these carbohydrates, as a result of which fermentation occurs in the distal ileum and colon. Lumen distension is the result of production of gas and an osmotic load. Staudacher et al., 2011, in his trial in IBS patients administered Low FODMAP diet in group 1 and standard diet in group 2. The results showed significant decrease in the symptom severity of patients who followed low FODMAP diet (76%) as compared to those who followed standard diet (54%). There was a considerable improvement in bloating of the group following low FODMAP diet (82%) when compared to standard group of patients(49%), abdominal pain (low FODMAP 85% v/s standard 61%) and flatulence (low FODMAP 87% v/s standard 50%). In a systematic review by Fairlie et al., 2023, there was a 47.3% prevalence of DGBI overlap in patients from tertaiary healthcare settings when compared to the cohort studies (26.5%). When compared to patients without overlap, the patients with DGBI overlap had lower quality of life. Also, the symptom severity of patients with overlap was more in comparioson to those

without overlap. There are four proposed FD overlap clusters across Asia-Pacific region, i) FD-GERD, ii) EPS-IBS, iii) PDS-IBS and iv) FD-Constipation with differing symptoms, pathophysiology and treatments(Gwee et al., 2023).

In a carefully designed, cross-over study by Halmos et al., 2014 of individuals suffering from IBS, diet low in FODMAPs effectively alleviated the symptoms of FGIDs like bloating, passage of gas etc. Patients of all subtype of IBS had greater satisfaction with stool consistency following a Low FODMAP diet. A study by Staudacher et al., 2021**,** established that administering a low FODMAP diet in patients with functional dyspepsia reduced their symptoms. When compared to individuals who received standard diet, those receiving low FODMAP dietary advice experienced a higher decrease in epigastric score (50% vs 16% - low FODMAP vs Standard). So et al., 2022 in his double blinded cross over study, supplemented 3 types of fiber in different quantities along with low FODMAP diet to overcome low fiber intake during the diet. He found out that this supplementation led to increased stool bulk, normal stool water content, and improvement in slower stool transit without altering the patient's symptomatic response.

Research Gap

Over the past decade, there have been number of studies concluding that the symptoms of gastrointestinal disorders like IBS and FD can get triggered by an increased intake of fermentable oligosaccharide, disaccharide, monosaccharide and polyols. This is attributed to the poor absorption of these carbohydrates in small intestines and their tendency to pass to colon without getting absorbed. This increases the luminal water by the activity of osmosis and promote production of gas on getting fermented by colonic bacteria. This causes luminal distension, leading to development of GI symptoms in more susceptible individuals. Apart from this the GI symptoms can also be the result of FODMAP affecting gut microbiota, gut barrier or function of gut immunity. Indian trials are demonstrating the effect of low FODMAP diet in individuals with IBS or FD separately but no such trial with the overlap of these two. Therefore, the main aim of this randomized open-label study is to see the effect of low FODMAP diet on symptom severity of patients with IBS-FD overlap.

Problem Statement

Indian trials are demonstrating the effect of low FODMAP diet in individuals with IBS or FD separately but no such trial with the overlap of these two. Therefore, the main aim of this randomized open-label study is to see the effect of low FODMAP diet on symptom severity of patients with IBS-FD overlap.

Research Objectives

1. To see the effect of following a low FODMAP diet in IBS-FD overlap patients when compared to traditional dietary advice.
2. To check for symptom improvement in IBS-FD overlap patients after following a low FODMAP diet when compared to traditional dietary advice.
3. To see improvement in quality of life in IBS-FD overlap patients after following a low FODMAP diet when compared to traditional dietary advice.
4. To note any adverse effect of following a low FODMAP diet in IBS-FD overlap patients.
5. To find out predictors of response to low FODMAP diet in IBS-FD overlap patients.

Research Methodology

Subjects

We will be following randomized open label study design to assess the efficacy of low fermentable oligosaccharide, disaccharide, monosaccharide and polyols (FODMAP) diet – a standardized diet given by Monash University in IBS-FD overlap patients.

n = 94

The primary outcome determines our sample size calculation. As there is a lack of researched data on efficacy of "Low FODMAP diet" in patients suffering from IBS-FD overlap, we will use data on effect of "Low FODMAP diet" in IBS, as it is a disorder closely related to IBS-FD overlap. The best response in terms of symptom reduction recorded for low FODMAP diet in IBS patients is approximately 68% and to Traditional Dietary Advice is about 40%. Taking into account logistic regression, 80% power assumption and two-sided significance level of 5%, we require 43 patients in each group. We will assume attrition rate of about 10%, therefore, minimum 47 patients are required in each group. The sample is calculated using M-Stat software.

Here GROUP 1 is Low FODMAP diet and GROUP 2 is Traditional Dietary advice.

PATIENTS

Inclusion criteria

1. **P**resence of both, IBS and FD with symptoms (As per Rome IV criteria)
2. Age group- 18 to 50 years
3. Willing to participate and give written informed consent.

Exclusion criteria

1. History of any other gastrointestinal co-morbidity diagnosed through any prior endoscopy, celiac disease, long term consumption of NSAIDS/ salicylates, intestinal parasitic/ other infections, history of food allergies, any significant addictions, or significant co-morbidities.
2. Pregnant or lactating females
3. Patients with BMI less than 18.5 kg/m 2

4. Patients with alarming symptoms like unintentional weight loss (>5% during last
   month), dysphagia, anemia, persistent/ recurring vomiting, hematemesis, melena
   and severe abdominal pain.
5. History of lactose/fructose intolerance. Patients following a prior restricted diet (e.g. LFD, gluten-free diet, lactose-free diet)

Step 1: Screening patients for IBS-FD overlap

- The first step will be to administer Rome IV for the diagnosis of IBS and FD in patients from the outpatient department of the gastroenterology department of a Govind Ballabh Pant Hospital, Dr. Ram Manohar Lohia Hospital of New Delhi, India and Dayanand Medical College, Ludhiana India

Step 2: **Assessing symptom severity and quality of life**

Out of the screened patients, ones falling under the category of IBS-FD overlap will be further assessed for symptom severity and quality of life

- Administration of Short-form Nepean Dyspepsia Index (SF-NDI) questionnaire for symptom severity and quality of life (QOL) for functional dyspepsia (Goyal et.al., 2022)
- Administration of irritable bowel syndrome severity score (IBSSS) to assess extent symptom and IBS- QOL for quality of life in IBS (Goyal et.al., 2021)

Step 3: Dietary recall and food diary

The patients willing to participate will be asked a 3-day dietary recall for average nutrient intake.

They will be asked to maintain a food diary wherein they will journal each meal and snack they eat followed by any symptom that followed.

Step 4: Allocation of the diet

The patients will be randomly given either of the two diets. One group will be given low FODMAP diet and another group will be given traditional dietary advice- i) restrict the intake of tea, coffee, aerated drinks, spices, alcohol, tobacco ii) limit the intake of dairy iii) have small meals.

Phases of low FODMAP diet intervention-

Phase 1: Elimination Phase (6 weeks)

Foods high in FODMAPS will be removed from the diet of the patients given Low FODMAP diet. Foods will be categorized Low/High FODMAP with the help of Monash University application of Low FODMAP dietary guide.

After 6 weeks, diary with food and symptoms record will be collected, and patient will complete SF-NDI , IBSSS, IBS-QOL questionnaires. Difficulties in following the diet and adverse events if any will be noted. Compliance to the Diet will be evaluated using following categories: "rarely (< 25% time), sometimes (25–50% time), frequently (51–75% time), or always (76–100% time)". Patients found to be compliant with dietary advice > 50% of time will go on to phase 2. Low FODMAP diet group will receive the modified instructions related to the FODMAP phase, while Traditional Dietary Advice group will continue with same instructions.

Phase 2: Re- introduction Phase (6 weeks)

Each FODMAP subgroup- lactose, fructose, polyols, fructans, galacto-oligosaccharide will be reintroduced in the diet of the patient each week with set quantities of toleration giving a settling period of 2 days between reintroduction of each group. Each patient will journal the symptoms; if any, arises from any FODMAP subgroup.

End of the study (12 weeks). diary with food and symptoms record will be collected, and patients will be asked to complete SF-NDI, IBSSS, IBS-QOL questionnaire. Dietary compliance and adverse events will be noted. Average daily dietary intakes- energy, macronutrients, dietary fibres, and FODMAPs will be calculated at baseline, 6 weeks, and 12 weeks.

Results and Expected Outcome

It is expected that people suffering from IBS-FD overlap will benefit from the Low FODMAP diet in terms of reduction in symptom severity, ease of comfort and increased quality of life.

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Effect of Low FODMAP Diet on irritable bowel syndrome and functional dyspepsia overlap.

SHORT SYNOPSIS

by

Riya Khurana
12103MRIIRSPHD1N006

Under the supervision of

Dr. Gurseen Rakhra
Assistant Professor
Department of Nutrition and Dietetics
Faculty of Allied Health Sciences

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ABSTRACT

Evidence from various researches have suggested the association between the consumption of food rich in "fermentable oligosaccharide, disaccharide, monosaccharide and polyols" with symptoms arising from irritable bowel syndrome (IBS) as well as functional dyspepsia (FD). Although, the pathophysiology of IBS as well as FD is limited to none, current knowledge associates it with altered function of the gut barrier, impaired intestinal and gastroduodenal sensitivity, intestinal and gastroduodenal inflammation and dysbiosis of the gut microbiota. Clinically, there is an increased probability of IBS-FD overlap in case of severe gastrointestinal symptoms like pain in the abdomen and/or disordered bowel habit with treatments

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that are aimed to reduce these symptoms. Certain dietary components are thought to exacerbate their symptoms. Therefore, there has been an emphasis on dietary management of the condition. There has been a paradigmatic shift in the treatment of IBS and FD with the introduction of diet "low in fermentable oligosaccharide, disaccharide, monosaccharide and polyols"- "low FODMAP diet". Various experimental studies have used low FODMAP diet as an intervention to treat IBS or FD. However, there is a critical need for a study to substantiate if low FODMAP diet is beneficial for treating IBS-FD overlap. There is no trial as per our search to evaluate the impact of low FODMAP diet on the overlap of IBS and FD. Apart from this, there is no data that evaluates "the reintroduction phase" of the low FODMAP intervention in IBS-FD overlap. Therefore, through this research we would like to build an association between reduced symptoms of IBS-FD overlap with a low FODMAP diet in comparison to traditional dietary advice.

Keywords: IBS, dyspepsia, low FODMAP, gut dysbiosis, IBS-FD overlap

IBS-FD overlap

by Gurseen Rakhra

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30,533	4,604	250	18 min 24 sec	35 min 24 sec
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5th February, 2024

Dr.Gurseen Rakhra
Supervisior
Assistant Professor
Department of Nutrition & Dietetics,
School of Allied Health Sciences
MRIIRS,
Faridabad- 121001

Dear Dr. **Gurseen Rakhra**
The MRIIRS Ethics Committee has reviewed your request, for the ethical approval for the research project outlined below.

" Effect of Low FODMAP Diet on irritable bowel syndrome and functional dyspepsia overlap. ."

Ms. Riya Khurana
Research Scholar
MRIIRS
Registration number: 12103MRIIRSPHD1N006

The case is discussed in the meeting of Ethical Committee, MRIIRS held on 27/12/2023 vide Online Mode at 10.00 am.

https://meet.google.com/afw-bphq-hwz

Further, on examining the research work undertaken vide video presentation mode given by the Research Scholar, as indicated above , it was resolved that ethical approval may be granted as the research scholar will obtain consent of participants i.e. male and female, 18 to 50 years, with irritable bowel syndrome and functional dyspepsia overlap . Also consent letter format / form both English,Hindi and Punjabi has been submitted. The form and certificate can be used for

carrying out a multi centric research study involving Govind Ballabh Pant Hospital,Delhi, Ram Manohar Lohia Hospital,Delhi and Dayanand Medical College & Hospital. Ludhiana

The required documents as asked in the meeting have been submitted today i.e. 05.02.2024 by Dr. Gurseen Rakhra , Assistant Professor, Supervisor, School of Allied Health Sciences. MRIIRS

Approval No:	EC/2023-24/045
Approval Date:	05/02/2024
Expiry Date:	01/02/2027
Ethics Committee Decision	Approved

The standard conditions of this approval are:

a) Conduct the project strictly in accordance with the proposal submitted and granted ethics approval. Including any amendments made to the proposal required by the MRIIRS Ethics Committee.

b) Report (email: dean.research@mriu.edu.in) immediately of any complaints or other issues in relation to the research project which may warrant review of the ethical approval of the project.

c) provide a 'progress report' for every year of approval.
d) provide a 'final report' when the project is complete.
e) advise in writing if the project has been discontinued

Please note that failure to comply with the conditions of approval and the **"INDIAN COUNCIL OF MEDICAL RESEARCH. 2017. NATIONAL ETHICAL GUIDELINES. FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN"** may result in withdrawal of approval for the research project.

Sarita 5/2/24.

Dr Sarita Sachdeva
ED & Dean Research
MRIIRS

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